



Food and Drug Administration
Rockville MD 20857

FEB 24 2005

Cristina Neves, Regulatory Affairs Director
Hikma Farmacêutica (Portugal), Lda.
Estrada do Rio da Mó, nº 8, 8A-8B
Fervença
2705-906 TERRUGEM SNT PORTUGAL

Re: Docket Nos. 2004P-0406/CP1 and
2004P-0407/CP1

Dear Ms. Neves:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your two citizen petitions submitted on September 7, 2004. Your petitions request that the Agency determine (1) whether Celestone (betamethasone sodium phosphate) injection equivalent to 3 mg base/mL (NDA 17-561) has been voluntarily withdrawn from sale for safety or efficacy reasons, and (2) whether Celestone Soluspan (betamethasone sodium phosphate plus betamethasone acetate) injection equivalent to 6 mg base/mL (NDA 14-602) has been voluntarily shortened from distribution and sale for safety or efficacy reasons.

FDA has been unable to reach a decision on your petitions due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petitions as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0407

LET 1